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U.S. NUCLEAR REGULATORY COMMISSION
STANDARD REVIEW PLAN
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS

3.0 INTEGRATED SAFETY ANALYSIS (ISA) AND ISA SUMMARY

3.1 PURPOSE OF REVIEW

An Integrated Safety Analysis (ISA) identifies potential accident sequences in the facility=s operations, designates items relied on for safety (IROFS) to either prevent such accidents or mitigate their consequences to an acceptable level and describes management measures to provide reasonable assurance of the availability and reliability of IROFS. Applicants for new licenses and persons holding 10 CFR Part 70 licenses on September 18, 2000 must perform an ISA and submit a summary of it B referred to as an >ISA Summary= B to NRC, for approval. The ISA Summary principally differs from the ISA by focusing on higher risk accident sequences whose consequences could exceed the performance criteria of 10 CFR 70.61.

The ISA and supporting documentation (such as piping and instrumentation diagrams, criticality safety analyses, dose calculations, process safety information and ISA worksheets) are, maintained at the facility. The NRC determines the acceptability of the applicant=s ISA. The NRC does this by reviewing and approving the applicant=s ISA Summary which, although not part of the license application, is placed on the public docket. Neither the ISA, nor ISA Summary, is incorporated as part of the license.

Reviewers must confirm that an ISA Summary meets the regulatory requirements of 10 CFR 70.65 and, specifically, that suitable IROFS and management measures have been designated for higher risk accident sequences and that programmatic commitments to maintain the ISA and ISA Summary are acceptable. An applicant may submit, for NRC approval, one ISA Summary for the entire facility, or multiple ISA Summaries for individual processes (or groups of processes) in the facility as they are completed. Reviews of ISA Summaries may necessitate examination of the ISA and its supporting documentation to confirm the underpinnings of calculations, conclusions and components of safety programs.

This chapter provides guidance for staff review of two types of information submitted by licensees or applicants:

1) Commitments regarding the applicant=s Safety Program including the ISA, pursuant to the requirements of 10 CFR 70.62, and

2) ISA Summaries submitted in accordance with 10 CFR 70.62(c)(3)(ii) and 70.65.

In the case of license applications (either initial or for renewal), both types of information would be submitted. In the case of a license amendment, either or both types of information may be

submitted, as needed, to address the areas amended.

Safety Program and ISA Commitments

The purpose for the review of commitments relative to the Safety Program, including the ISA, as presented in the license application, renewal, or amendment, is to determine with reasonable assurance that the applicant will accomplish the requirements of 10CFR: 70.61; 70.62(a)(1), (2), and (3); 70.62(c)(1), and (2); 70.62(d); 70.64 for new facilities; and 70.72 for changes requiring updates of their ISA.

ISA Summary

The purpose of the review of the ISA Summary is to establish reasonable assurance that the applicant has performed the following tasks.

1. Conducted an ISA of appropriate detail for each applicable process, using methods and staff adequate to achieve the requirements of 10 CFR 70.62(c)(1) and (2).

2. Identified and evaluated, in the ISA, all credible events (accident sequences) involving process deviations or other events internal to the plant (e.g., explosions, spills, and fires); and credible external events that could result in facility-induced consequences to the public, worker, or the environment, that could exceed the performance requirements of 10 CFR 70.61. External events normally include, as a minimum:

   (1) Natural phenomena events such as floods, high winds, tornadoes, and earthquakes;
   (2) Fires external to the facility; and
   (3) Transportation accidents and accidents at nearby industrial facilities.

3. Designated engineered and administrative IROFS, and correctly evaluated the set of IROFS addressing each accident sequence, as providing reasonable assurance, through preventive or mitigative measures, and through application of supporting management measures (discussed in Chapter 11) that the performance requirements of 10 CFR 70.61 are met.

3.2 RESPONSIBILITY FOR REVIEW

Primary: Assigned staff licensing reviewer

Secondary: Technical specialists in specific areas

Supporting: Fuel Facility Inspection Staff

3.3 AREAS OF REVIEW

Two types of submittals are addressed by this chapter of the SRP, (1) submittals containing descriptive commitments regarding the Safety Program, including the ISA; and (2) ISA Summaries. The descriptive commitments regarding the Safety Program should be found in license applications, renewals, and amendments. ISA Summaries may be submitted for an entire existing facility, a new facility, a new process, or for altered processes requiring revision of the ISA.

The Safety Program and ISA commitments and descriptions to be reviewed consist of: 1) process safety information [10 CFR 70.62(b)]; 2) methods used to perform the ISA; 3) qualifications of the team performing the ISA [10 CFR 70.62(c)(2)]; 4) methods of documenting and implementing the results of the ISA; 5) procedures to maintain the ISA current when changes are made to the facility; and 6) management measures [10 CFR 70.62(d)]. These commitments and descriptions, as appropriate, will be documented primarily within an ISA chapter, in the license application. However, commitments and descriptions regarding management measures will be in a separate chapter of an application, pursuant to Chapter 11 of this SRP.

The results of ISA analyses performed for compliance with the rule are presented in an ISA Summary. This ISA Summary may be submitted with an application for a new license, a license renewal, or a license amendment, but is not to be incorporated as part of the license.

The ISA Summary submitted to the NRC, and portions of the ISA documentation maintained onsite, will be reviewed to determine the adequacy of the applicant's ISA. The contents of the ISA Summary are specified in 10 CFR 70.65 and include the following nine topics:

(1) general description of the site
(2) general description of the facility
(3) description of facility processes
(4) demonstration of compliance with 10 CFR 70.61 performance requirements
(5) description of the ISA Team and their qualifications
(6) descriptive list of IROFS
(7) description of acute chemical exposure standards used
(8) descriptive list of sole IROFS
(9) definition of the terms: credible, unlikely, highly unlikely

The ISA and supporting documentation used in its preparation (e.g., piping and instrumentation drawings, engineered IROFS boundary descriptions, criticality safety analyses, dose calculations, process hazards analysis, process safety information, ISA worksheets, etc.) will be maintained at the facility site. The reviewer may need to consult the ISA and supporting documentation at the facility site to establish the completeness and acceptability of the ISA, or, in the case of an existing facility, to visit the site to fully understand a process operation. For example, the reviewer should confirm that low-risk accident sequences not reported in the ISA Summary were correctly identified and analyzed in the ISA.

3.3.1 Safety Program and ISA Commitments

The staff reviews the application to determine whether the applicant=s commitments to establish a safety program and to perform and maintain an ISA are adequate. In the following, the phrases Aprocess node@ or Aprocess@ are used to refer to a single reasonably compact piece of equipment or workstation where a single unit process or processing step is conducted. A typical fuel cycle facility is divided into several major process lines or areas, each consisting of many process nodes. The areas of review for ISA commitments are as follows:

1. The applicant's description of, and commitments to, a method for maintaining a current and accurate set of process safety information, including information on the hazardous materials, technology, and equipment used in each process. The applicant should explain this activity

in detail in the description of its configuration management program (Section 11.1, AConfiguration Management@).

2. The applicant's description of, and commitments to, requirements for ISA team training and qualifications (Section 11.4, ATraining and Qualification@) for those individuals who will conduct and maintain the ISA and ISA Summary.

3. The applicant's description of, and commitments to, ISA methods, method selection criteria, or specific methods to be used for particular classes of process nodes (usually process workstations). The review of the ISA methodology includes evaluating the applicant=s methods in the following specific areas:

   a. Hazard identification;

   b. Process hazard analysis (accident identification);

   c. Accident sequence construction and evaluation;

   d. Consequence determination and comparability to 10 CFR 70.61; and

   e. Likelihood categorization for determination of compliance with 10 CFR 70.61.

4. The applicant's description of, and commitments to, management procedures for conducting and maintaining the ISA. Specific review areas include the applicant's procedures for:

   (1) performance of, and updates to, the ISA;
   (2) review responsibility;
   (3) ISA documentation;
   (4) reporting of ISA Summary changes per 10 CFR 70.72(d)(1) and (3); and
   (5) maintenance of ISA records per 10 CFR 70.62(a)(2).

3.3.2 ISA Summary

The staff reviews the ISA Summary and, if necessary, other ISA documentation to find reasonable assurance that the applicant has performed a systematic evaluation of the hazards and credible accident sequences; and has identified IROFS and management measures that satisfy the performance requirements of 10 CFR 70.61. The review boundary includes those accidents that result in a release of radioactive material, a nuclear criticality event, or any other exposure to radiation resulting from use of licensed material. In addition, the staff reviews accidents involving hazardous chemicals produced from license materials. That is, chemicals that are licensed materials, or have licensed materials as precursor compounds, or substances that physically or chemically interact with licensed materials, and that are toxic, explosive, flammable, corrosive, or reactive to the extent that they endanger life or health. These include substances that are commingled with licensed material or are produced by a reaction with licensed material. If a chemical accident has the potential to cause, or reduce protection from, a radiation exposure accident, then it also must be addressed. On the other hand, accident sequences having unmitigated consequences that will not exceed the performance requirements of 10 CFR 70.61(c), once identified as such, do not require reporting in the ISA Summary.

The areas of review for the ISA Summary are as follows:

1. SITE: The site description in the ISA Summary (see Section 1.3, "Site Description") concerning those factors that could affect safety, such as geography, meteorology (e.g., high winds and flood potential), seismology, demography, and nearby industrial facilities and transportation routes.

2. FACILITY: The facility description in the ISA Summary concerning features that could affect potential accidents and their consequences. Examples of these features are facility location, facility design information, and the location and arrangement of buildings on the facility site.

3. PROCESSES: The description in the ISA Summary of each process analyzed as part of the ISA. Specific areas reviewed include basic process function and theory, functions of major components and their operation, process design and equipment, and process operating ranges and limits. Also to be provided is a list of the hazards (and interactions of hazards) for each process and the accident sequences that could result from such hazards and whose unprevented / unmitigated consequences could exceed the performance requirements of 10 CFR 70.61.

4. DEMONSTRATION OF COMPLIANCE WITH 10 CFR 70.61: The information developed in the ISA that demonstrates compliance with the performance criteria of 10 CFR 70.61. This information includes for each applicable process:

   a) The postulated consequences and comparison to the consequence levels identified in 10 CFR 70.61. Information, such as inventory and release path factors, supporting the results of the consequence evaluation.

   b) Information showing how the likelihoods of accident sequences that could exceed the performance requirements of 10 CFR 70.61 were established.

   c) Information describing how designated IROFS protect against accident sequences that could exceed the performance requirements of 10 CFR 70.61.

   d) Information on management measures applied to the IROFS (addressed in greater detail in Chapter 11)

   e) Information on how the criticality monitoring requirements of 10 CFR 70.24 are met, and

   f) If applicable, how the baseline design criteria of 10 CFR 70.64 are addressed.

5. TEAM QUALIFICATIONS AND ISA METHODS: The applicant=s ISA Team qualifications and ISA methods as described in the ISA Summary. If methods are adequately described in the license application, there will be no need to duplicate this information in the ISA Summary. Documentation of specific example of the application of methods may be requested or reviewed on site to confirm understanding of specific methods.

6. LIST OF IROFS: The list, in the ISA Summary, describing the IROFS for all intermediate- and

high-consequence accidents in sufficient detail to understand their safety function.

7. CHEMICAL CONSEQUENCE STANDARDS: The applicant=s quantitative standards for assessing the chemical consequence levels specified in 10 CFR 70.61, as described in the ISA Summary.

8. LIST OF SOLE IROFS: The list, in the ISA Summary, identifying those IROFS that are the sole item preventing or mitigating an accident whose consequences could exceed the performance requirements of 10 CFR 70.61.

9. DEFINITIONS OF UNLIKELY, HIGHLY UNLIKELY AND CREDIBLE: The applicant=s definitions of unlikely, highly unlikely, and credible used in 10CFR 70.61.

10 CFR 70.65(b) lists the types of information required to be submitted in an ISA summary. This includes generic information, such as site description, ISA methods, and ISA team qualifications. This also includes process-specific information such as a list of IROFS, general descriptions of accident types, and "information demonstrating compliance with 10 CFR 70.61." To meet the "information demonstrating compliance with 10 CFR 70.61" requirement, an applicant or licensee would have to provide, as a minimum, process-specific likelihood and consequence evaluation information for a representative sample of diverse processes to permit the reviewer to evaluate the effectiveness of the licensee's likelihood and consequence evaluation methods.

In some simple cases, the information normally contained in the process descriptions and list of IROFS might be sufficient to understand how compliance is achieved when taken together with the description of ISA likelihood evaluation methods and criteria. However, in general, some kind of summary or statement of why the licensee ISA team evaluated all accidents as "highly unlikely" and/or "unlikely" needs to be supplied for each process individually. That is, most often, each individual process would be expected to be addressed in the ISA Summary with respect to summarizing its likelihood evaluation.

In addition, it is necessary that the staff reviewer evaluate the efficacy of the licensee's ISA methods. In addition to the description of the ISA methods, the reviewer will need to see how these methods have been applied in practice to the wide diversity of process safety designs in the facility. Details regarding the application of the methods to a representative sample of processes would allow the reviewer to make a determination of adequacy of the methods. In addition, it would place the reviewer in a better position to select other processes for which additional "vertical slice" reviews may need to be performed onsite. For an average sized fuel fabrication facility, a detailed demonstration of the application of the ISA methods to three or four processes from the standpoint of nuclear criticality safety, one process from the standpoint of fire safety, and one process from the standpoint of radiological and/or chemical safety, may be sufficient. Clearly, the number of examples needed in the ISA Summary would depend upon the diversity of process designs and IROFS that exist at a certain facility.

The NRC review of the licensee's evaluation of a number of diverse process designs, which have been selected by the licensee, is not a substitute for the "vertical and horizontal" slice reviews based on fully detailed information at the site. This on-site evaluation must be NRC-selected in order to be a confirmation of the fact that the ISA was actually implemented as described in the ISA Summary.

The method for selecting specific processes or accidents for additional review is described in

Section 3.5 of this chapter, “Review Procedures.”

3.4 ACCEPTANCE CRITERIA

3.4.1 Regulatory Requirements

The requirement to establish and maintain a safety program, including performance of an ISA, is specified in 10 CFR 70.62. 10 CFR 70.62(c) specifies requirements for the tasks comprising the ISA and the evaluation that credible high-consequence and intermediate-consequence events meet the safety performance requirements of 10 CFR 70.61. The requirement to prepare and submit an ISA Summary for NRC approval is stated in 10 CFR 70.65(b). 10 CFR 70.65(b) also describes the contents of an ISA Summary. 10 CFR 70.72 sets forth requirements for keeping the ISA, the ISA documentation and the ISA Summary current when changes are made to the site, structures, processes, systems, equipment, components, computer programs, and activities of personnel.

The information to be included in the ISA Summary can be divided into four categories: (i) site and facility characteristics; (ii) ISA methodology; (iii) hazards and accident analysis; and (iv) IROFS. The information requirements of each category, the corresponding regulatory citation, and the section of NUREG-1520, Chapter 3, in which the expectations for such information are described, are presented below.

Information Requirements for the ISA Summary and Corresponding Part 70 and NUREG-1520 Citations

Information Category and Requirement	10 CFR Part 70 Regulatory Citation	NUREG-1520, Chapter 3 Section Reference
Site and Facility Characteristics:		
$Site description	70.65(b)(1)	3.4.3.2(1)
$Facility description	70.65(b)(2)	3.4.3.2(2)
$Criticality monitoring and alarms	70.65(b)(4)	3.4.3.2(3)
$Compliance with baseline design criteria	70.64 (if applicable)	3.4.3.2(3)
ISA Methodology:		
$ISA methodology description	70.65(b)(5)	3.4.3.2(5)
$ISA team description	70.65(b)(5)	3.4.3.2(5)
$Quantitative standards for acute chemical exposures	70.65(b)(7)	3.4.3.2(7)
$Definition of unlikely, highly unlikely, and	70.65(b)(9)	3.4.3.2(9)
***Hazards and Accident Analysis*:**		
$Description of processes analyzed	70.65(b)(3)	3.4.3.2(3)
$Identification of hazards	70.65(b)(3)	3.4.3.2(3)
$Description of accident sequences	70.65(b)(3)	3.4.3.2(3)
$Characterization of high- and intermediate-consequence accident sequences	70.65(b)(3)	3.4.3.2(3)
***Items Relied on For Safety*:**		
$List and description of items relied on for safety (IROFS)	70.65(b)(6)	3.4.3.2(6)
$Description of IROFS' link to accident sequences to show 10 CFR 70.61 compliance	70.65(b)(6)	3.4.3.2(6)
$IROFS management measures	70.65(b)(4)	3.4.3.2(6)
$List of sole IROFS	70.65(b)(8)	3.4.3.2(8)

3.4.2 Regulatory Guidance

Guidance applicable to performing an ISA and documenting the results is contained in NUREG-1513, "Integrated Safety Analysis Guidance Document." NUREG/CR-6410, ANuclear Fuel Cycle Accident Analysis Handbook,@ March 1998, provides guidance on acceptable methods for evaluating the chemical and radiological consequences of potential accidents.

3.4.3 Regulatory Acceptance Criteria

The acceptance criteria for an ISA are based on meeting the relevant requirements of 10 CFR 70, “Domestic Licensing of Special Nuclear Material.” The ISA will form the basis for the safety program by identifying potential accidents, designating IROFS and management measures, and evaluating the likelihood and consequences of each accident sequence for compliance with the performance requirements of 10 CFR 70.61. Some of the acceptance criteria address the programmatic commitments made by the licensee to perform and maintain an ISA. The remainder of the criteria address the ISA results, as documented in the ISA Summary, and whether those documented results demonstrate that the applicant=s IROFS and management measures can reasonably be expected to assure that the relevant accident sequences will meet the performance requirements of 10 CFR 70.61.

3.4.3.1 Safety Program and ISA Commitments

License commitments pertaining to the facility's Safety Program, including the performance of an ISA, are presented in this Section 3.4.3.1. 10 CFR Part 70 contains a number of specific safety program requirements related to the ISA. Acceptance criteria for those requirements addressed by contents of the ISA Summary appear in Section 3.4.3.2. These include the primary requirements that an ISA be conducted, and that it evaluate and show that the applicant=s facility complies with the performance requirements of 10 CFR 70.61. Acceptance criteria for the other ISA requirements are provided in this Section 3.4.3.1. For each component of the Safety Program there may be several necessary elements, including, for example, organization, assignment of responsibilities, management policies, required activities, written procedures for activities, use of industry consensus standards, and technical safety practices.

The applicant=s commitments for each of the three elements of the Safety Program defined in 10 CFR 70.62(a) should be acceptable if the applicant does the following:

A. Process Safety Information

1. The applicant commits to compile and maintain an up-to-date database of process-safety information. Written process-safety information will be used in updating the ISA and in identifying and understanding the hazards associated with the processes. The compilation of written process-safety information shall include information pertaining to:

    a. The hazards of all materials used or produced in the process. Information on chemical and physical properties such as toxicity, acute exposure limits, reactivity, and chemical and thermal stability such as are included on Material Safety Data Sheets [meeting the requirements of 29 CFR 1910.1200(g)] should be provided.

    b. Technology of the process. Information on the process technology should include a

block flow diagram or simplified process flow diagram; a brief outline of the process chemistry; safe upper and lower limits for controlled parameters (e.g., temperature, pressure, flow, and concentration); and evaluation of the health and safety consequences of process deviations.

c. Equipment used in the process. Information of a general nature on topics such as the materials of construction; piping and instrumentation diagrams (P&IDs); ventilation; design codes and standards employed; material and energy balances; IROFS (e.g., interlocks, detection, or suppression systems); electrical classification; and relief system design and design basis should be provided.

2. The applicant includes procedures and criteria for changing the ISA, along with its commitment to design and implement a facility change mechanism that meets the requirements of 10 CFR 70.72. The applicant should discuss the evaluation of the change within the ISA framework, and procedures and responsibilities for updating the facility ISA.

3. The applicant commits to engage personnel with appropriate experience and expertise in engineering and process operations to maintain the ISA. The ISA team for a process shall consist of individuals knowledgeable in the facility=s ISA methodology and in the operation, hazards, and safety design criteria of the particular process.

4. The applicant commits to conduct an ISA of appropriate complexity for each process such that it identifies (i) radiological hazards, (ii) chemical hazards that could increase radiological risk, (iii) facility hazards that could increase radiological risk, (iv) potential accident sequences, (v) consequences and likelihood of each accident sequence and (vi) IROFS including the assumptions and conditions under which they support compliance with the performance requirements of 10 CFR 70.61. The application is acceptable if it describes sufficiently specific methods and criteria that would be effective in accomplishing each of these tasks. Such effective methods and criteria are described in NUREG-1513, NUREG-6410, item 5 of SRP section 3.4.3.2, and Appendix A of this chapter.

B. ISA

1. The applicant commits to maintain the ISA and ISA supporting documentation accurate and up-to-date by means of a suitable configuration management system and to submit changes in the ISA Summary, to NRC, in accordance with 10 CFR 70.72(d)(1) and (3). The ISA must account for any changes made to the facility or its processes (e.g., changes to the site, operating procedures, or control systems). Management policies, organizational responsibilities, revision time frame, and procedures to perform and approve revisions to the ISA should be outlined succinctly. The applicant commits to evaluating any facility changes or changes in the process safety information that may alter the parameters of an accident sequence by means of the facility=s ISA methodology. For any revisions to the ISA, the applicant commits to using an ISA Team with member qualifications similar to those used in conducting the original ISA.

2. The applicant commits to train personnel in the facility's ISA methodology(ies) and/or to use suitably qualified personnel for updating and maintaining the ISA and ISA Summary.

3. The applicant commits to evaluate proposed changes to the facility or its operations by means of the ISA methodology(ies) and to designate new or additional IROFS and

appropriate management measures as required. The licensee also agrees to promptly evaluate the adequacy of existing IROFS and associated management measures and to making any required changes that may be impacted by changes to the facility and/or its processes. If a proposed change results in a new type of accident sequence (e.g., different initiating event, and significant changes in the consequences) or increases the risk of a previously analyzed accident sequence within the context of 10 CFR 70.61, the applicant commits to promptly evaluating the adequacy of existing IROFS and associated management measures and to making necessary changes, if required.

4. The applicant commits to address any unacceptable performance deficiencies that are identified through updates of the ISA.

5. The applicant commits to maintaining written procedures on site for carrying out that function, if necessary.

6. The applicant commits to implement all IROFS (if not already implemented) and to maintain them so that they are available and reliable when needed.

In citing industry consensus standards, the applicant should delineate specific commitments in the standards which will be adopted. The applicant should provide justifications if a standard is not adopted in its entirety.

C. Management Measures

1. The applicant commits to implement all IROFS (if not already implemented) and to maintain them so that they are reliable and available when needed.

2. The applicant commits to establish management measures (which are evaluated using SRP Chapter 11) which comprise the principal mechanism by which the reliability and availability of each IROFS are assured.

3.4.3.2 ISA Results, Including ISA Summary

Information in the ISA Summary should provide the basis for the staff=s conclusions that there is reasonable assurance that the identified IROFS will satisfy the performance requirements of the rule. However, the basis for the staff conclusion would not be limited to a determination that the applicant=s ISA program has the capability only to identify the appropriate IROFS. Rather, the focus of the staff review would be on the sufficiency of the IROFS identified in the ISA Summary. This requires a determination of whether the identified IROFS are adequate to control the potential accidents of concern at the facility. The accidents of concern are those whose consequences would be at the high and intermediate consequence levels, absent any preventive or mitigative controls. In this context, adequacy means the capability of the IROFS to prevent the related accidents with sufficient reliability, or to sufficiently mitigate their consequences. To support such a review, the information in the ISA Summary needs to provide enough information concerning the accidents to which the IROFS relate to be able to assess their contributions to prevention or mitigation. To do so, sufficiently detailed information for high and intermediate consequence accident sequences must be supplied to enable the staff reviewer to understand the preventive or mitigative function of each IROFS. The ISA Summary must contain enough information concerning the ISA procedures, methods, and human resources employed to have confidence that the potential accidents identified are reasonably complete.

In addition, staff needs to determine that appropriate management measures will be in place that will ensure the availability and reliability of the identified IROFS. Review of designated management measures is addressed in SRP Chapter 11.

The following acceptance criteria address each of the content elements of the ISA Summary required by 10 CFR 70.65(b). For new facilities it is expected that the staff reviewing the ISA Summary will also evaluate those aspects of the design that address those baseline design criteria of 10 CFR 70.64 which apply to individual processes. Thus the content elements for which there are acceptance criteria include:

1) general description of the site,
2) general description of the facility,
3) description of facility processes, hazards, accident sequences,
4) demonstration of compliance with 10 CFR 70.61 performance requirements,
5) description of the ISA team and methods,
6) descriptive list of IROFS,
7) description of acute chemical exposure standards used,
8) descriptive list of sole IROFS, and
9) definitions of unlikely, highly unlikely, and credible.

Detailed acceptance criteria for each element of the ISA Summary follow:

1. SITE

The description in the ISA Summary of the site for processing nuclear material is considered acceptable if the applicant includes, or references, the following safety-related information, with emphasis on those factors that could affect safety:

a. A description of the site geography, including its location, taking into account prominent natural and man-made features such as mountains, rivers, airports, population centers, possibly hazardous commercial and manufacturing facilities, transportation routes, etc., adequate to permit evaluation of: i) the likelihoods of accidents caused by external factors; and ii) the consequences of potential accidents.

b. Population information, based on recent census data, that shows population distribution, as a function of distance from the facility, adequate to permit evaluation of regulatory requirements, including exposure of the public to consequences listed in 10 CFR 70.61.

c. Characterization of natural phenomena (e.g., tornadoes, hurricanes, floods, and earthquakes) and other external events sufficient to assess their impact on plant safety and to assess their likelihood of occurrence. At least the 100-year flood should be postulated, consistent with U.S. Army corps of Engineers flood plain maps. The applicant also describes the maximum earthquake magnitude, peak ground acceleration, and return period expected at the site, for existing facilities. The applicant also provides earthquake accelerations on the site associated with a 250-year and 500-year earthquake on the nearest capable fault for new facilities and processes, to determine its resulting consequences for the structural integrity of the facility. The discussion identifies all design basis natural events for the facility, indicates which events are considered incredible, and describes the basis for that determination. The assessment also indicates which events could occur without adversely impacting safety.

2. FACILITY

The description of the facility is considered acceptable if the applicant identifies and describes the general features that affect the reliability or availability of IROFS. If such information is available elsewhere in the application, reference to the appropriate sections is considered acceptable. The information provided should adequately support an overall understanding of the facility structure and its general arrangement. As a minimum, the applicant adequately identifies and describes:

a. The facility location and the distance from the site boundary in all directions, including the distance to the nearest resident and distance to boundaries in the prevailing wind directions.

b. Restricted area and controlled area boundaries.

c. Design information regarding the resistance of the facility to failures caused by credible external events, when those failures may produce consequences exceeding those identified in 10 CFR 70.61.

d. The location and arrangement of buildings on the facility site.

3. PROCESSES, HAZARDS, AND ACCIDENT SEQUENCES

Processes

The description of the processes analyzed as part of the ISA [10 CFR 70.62(c)(1) (i-vi)] is considered acceptable if it describes the following features in sufficient detail to permit an understanding of the theory of operation, and to determine compliance with the performance requirements of the rule. A description at a systems level is acceptable provided it permits the staff to conduct adequately: 1) an evaluation of the completeness of the hazard and accident identification tasks; and 2) an evaluation of the likelihood and consequences of the accidents identified. If the information is available elsewhere in the application and is adequate to support the ISA, reference to the appropriate sections is considered acceptable. The information provides an adequate explanation of how the IROFS reliably prevent the process from exceeding safety limits for each high and intermediate consequence accident sequence.

a. Basic process function and theory. This information includes a general discussion of the basic theory of the process.

b. Major components-their function and operation. This information includes the general arrangement, function, and operation of major components in the process. It includes, if appropriate, arrangement drawings and process schematics showing the major components and instrumentation and, chemical flow sheets showing compositions of the various process streams.

c. Process design and equipment. This information includes a discussion of process design, equipment, and instrumentation that is sufficiently detailed to permit an adequate understanding of the results of the ISA. It includes, as appropriate, schematics indicating safety interrelationships of parts of the process. In particular, it is usually necessary for criticality safety to diagram the location and geometry of the fissile and other materials in the process, for both normal and bounding abnormal conditions. This can be done using either schematic drawings or textual descriptions indicating the location and geometry of

fissile materials, moderators, etc., sufficient to permit an understanding of how the IROFS limit the mass, geometry, moderation, reflection, etc. If such details are not included in the ISA summary, then the information may be verified as part of an on-site ISA review.

d. Process operating ranges and limits. This information includes the operating ranges and limits for measured process variables (e.g.,temperatures, pressures, flows, and compositions) that are controlled by IROFS to assure safe operations of the process. If such details are not included in the ISA summary, then the information may be verified as part of an on-site ISA review.

Hazards

The description of process hazards provided in the ISA Summary is acceptable if it identifies, for each process, all types of hazards relevant to determining compliance with the performance criteria of 10 CFR 70.61. That is, the acceptance criterion is completeness. All hazards that could result in an accident sequence whose consequences could exceed the performance requirements of 10 CFR 70.61 should be listed, even if later analysis of a particular hazard shows that resulting accident sequences do not exceed these minima. Otherwise the reviewer cannot determine completeness. General exclusion of consideration of certain hazards for an entire facility can be justified by bounding case analyses showing that, for the conditions or credible inventories on site, the performance requirements of 10 CFR 70.61 cannot be exceeded. In this case, the bounding inventories or conditions, if under the control of the applicant, become IROFS. The list of process hazards is acceptable if the ISA Summary provides:

1) A list of materials (radioactive, fissile, flammable, and toxic) or conditions that could result in hazardous situations (e.g., loss of containment of licensed nuclear material). The list includes maximum intended inventory amounts and the location of the hazardous materials at the facility.

2) Potential interactions between or among materials or conditions that could result in hazardous situations.

Accident Sequences

The general description of types of accident sequences in the ISA Summary is acceptable if the staff can determine:

a) That all accidents whose consequences could exceed the performance requirements of 10 CFR 70.61 have been identified; and

b) How the IROFS listed in the ISA Summary protect against each such type of accident.

General types of accident sequences differ if they consist of a different set of failures of IROFS. Thus several processes, each using a set of IROFS that is functionally of the same type (e.g., same mechanical, physical and/or electrical principle of operation), can be summarized as a single type of accident and listed only once. However, the individual processes covered by this system should be individually identified in a way that the reviewer can determine completeness in addressing all processes.

For this reason, it is not, in general, acceptable to merely list the type of hazard, or just the controlled parameters, without reference to the items relied on to control that parameter or hazard. The general description of accident sequences is acceptable if it covers all types of sequences of

initiating events and failures of IROFS. Initiating events may be either failure of an IROFS or an external event. Human errors can be initiating events or failures of IROFS. The accident description is acceptable if it permits the staff to determine how each accident sequence whose consequences could exceed the performance requirements of 10 CFR 70.61 is protected against by IROFS or a system of IROFS.

One acceptable way to do this is to show a fault tree on which the basic events are failures of the IROFS. Another acceptable way is to provide a table on which each row displays the events in an accident sequence, such as in Appendix A, Table A-6, where, in general, each event is failure of an IROFS. Another acceptable way is a narrative summary for each process describing the sequence of events in each type of accident.

To demonstrate completeness the general description of types of accident sequences must be identified by using systematic methods and consistent references. Therefore, each description of a general type of accident sequence is acceptable if:

a) An acceptable method of hazard identification and process hazard analysis was used in accordance with the criteria of NUREG-1513;

b) The selected method was correctly applied;

c) No accident sequence whose consequences could exceed the performance requirements of 10 CFR 70.61 was overlooked; and

d) A method of identifying plant processes was used that ensured identification of all processes.

During the early phases of an ISA, accidents will be identified whose consequences may initially be unknown. These accidents will later be analyzed and may be shown to have consequences less than the levels identified in 10 CFR 70.61.

It is not necessary to list as a separate type of accident sequence, every conceivable permutation of an accident. Accidents having characteristics that all fall in the same categories can be grouped as a single type of accident in the ISA Summary, if:

a) The initiating events have the same effect on the system;

b) They all consist of failures of the same IROFS or system of IROFS;

c) They all result in violation of the safety limit on the same parameter; and

d) They all result in the same type and severity categories of consequences.

4. INFORMATION DEMONSTRATING COMPLIANCE WITH THE PERFORMANCE REQUIREMENTS OF 10 CFR 70.61, INCLUDING: (A) MANAGEMENT MEASURES; (B) REQUIREMENTS OF CRITICALITY MONITORING; AND (C) REQUIREMENTS FOR NEW FACILITIES OR NEW PROCESSES AT EXISTING FACILITIES

A. Management Measures

10 CFR 70.65(b)(4) requires that the ISA Summary contain: Ainformation that demonstrates

compliance with the performance criteria of 10 CFR 70.61.@ Since the requirements of 10 CFR 70.61 are expressed in terms of consequences and likelihoods of events, the ISA Summary should provide sufficient information to demonstrate that:

a) Credible high-consequence events are highly unlikely; and

b) Credible intermediate-consequence events are unlikely.

The performance requirements of 10 CFR 70.61 have three elements: 1) completeness; 2) consequences; and 3) likelihood. These are discussed below.

Completeness

Completeness refers to the fact that each credible event must be addressed in the ISA. Consequences refers to the magnitude of the chemical and radiological doses of the accident and is the basis upon which an accident in classified in 10 CFR 70.61 to be a high or intermediate consequence event. Likelihood refers to the fact that 10 CFR 70.61 requires that intermediate-consequence events be unlikely, and high-consequence events be highly unlikely. Thus the information provided must address each of these three elements.

To be acceptable, the information provided must correspond to the ISA methods, consequence, and likelihood definitions described in the submittal. The information must show the basis and the results of applying these methods to each process. In addition, the information must show that the methods have been properly applied in each case.

The information showing completeness, consequences, and likelihood for accident sequences can be presented in various formats, including logic diagrams, fault trees or tabular summaries. Appendix A provides one example of how this information could be presented in an application.

Completeness is demonstrated by correctly applying an appropriate method of accident identification, as described in NUREG-1513, AISA Guidance Document.@ Completeness can be effectively displayed by using an appropriate diagram or description of the accidents identified. Specific acceptance criteria for completeness are covered in item 3 below.

Consequences

The information in the ISA Summary on consequences is acceptable for showing compliance with 10 CFR 70.61 if:

i. The information in the ISA Summary for each accident whose consequences could exceed the performance requirements of 10 CFR 70.61 includes an estimate of its quantitative consequences (doses, chemical exposures, criticality) in a form that can be directly compared with the consequence levels in 10 CFR 70.61; or includes a reference to a value documented elsewhere in the summary that applies to or bounds that accident;

ii. The consequences were calculated using a method and data consistent with NUREG-6410, ANuclear Fuel Cycle Facility Accident Analysis Handbook,@ March 1998, or using another method described and justified in the methods description section of the ISA Summary;

iii. All consequences that could result from the accident sequence have been evaluated. That is, if an accident can result in a range of consequences, then all possibilities must be considered, including the maximum source term and most adverse weather that could occur. However, if

such conditions are unlikely to occur, credit can be taken for this in the evaluation of likelihood; and

iv. The ISA Summary correctly assigns each type of accident to one of the consequence categories of 10 CFR 70.61; namely, high, or intermediate.

Unshielded nuclear criticality accidents are considered to be high-consequence events, because the radiation exposure that an individual could receive exceeds the acute 1 Sv (100 rem) dose of 10 CFR 70.61(b)(1). For processes with effective engineered shielding, criticalities may actually produce doses below the intermediate consequences of 10 CFR 70.61. As stated in the regulation, primary reliance must be on prevention of inadvertent nuclear criticalities. This applies notwithstanding shielding or other mitigative features. Therefore, regardless of the actual consequences, shielded criticalities must meet the likelihood criteria described in the following section of this SRP. If needed, the Nuclear Fuel Cycle Facility Accident Analysis Handbook (NUREG/CR-6410) provides methods for estimating magnitudes of criticality events that can be applied for workers or members of the public at varying distances from the event.

Likelihood

The information in the ISA Summary is acceptable for showing compliance with 10 CFR 70.61 if:

i. The ISA Summary contains a specification of the likelihood of each type of accident sequence that could exceed the performance requirements of 10 CFR 70.61;

ii. The likelihoods are derived from an acceptable method described in the ISA Summary=s methods section; and

iii. The likelihoods comply with acceptable definitions of the terms Aunlikely@ and Ahighly unlikely,@ as described in this SRP chapter. Note that, when interpreted as required accident frequencies, these terms refer to long-run average frequencies, not instantaneous values. That is, a system complies with the performance requirements of 10 CFR 70.61 as a long-run average. Otherwise failure of any IROFS, even for a very short period, would be a violation of the requirement, which is not the intent.

B. Criticality Monitoring

10 CFR 70.24 has specific sensitivity requirements for criticality monitors. To demonstrate compliance, the method for evaluating an acceptable response of at least two detectors to a nuclear criticality at any location where Special Nuclear Material (SNM) may be handled, used, or stored should be described. Locations of all detectors relative to the potential locations of SNM should be provided as a diagram. Information supporting determination of the gamma and neutron emission characteristics of the minimum credible accident of concern capable of producing the effects specified in 10 CFR 70.24 should be provided. Information showing the response characteristics of the detectors to neutron and gamma doses and rates characteristic of credible accidents should be given.

10 CFR 70.24 also requires specific emergency preparations. Information should be provided demonstrating that equipment and procedures of the applicant are adequate to assure that these requirements are met.

C. New Facilities

10 CFR 70.64 specifies baseline design criteria that must be used, as applicable, for new facilities and new processes at existing facilities. If the application involves such new facilities or processes, then the ISA Summary should explain how each baseline design criterion was addressed in the design of the facility. For deterministic design criteria such as double-contingency, the process-specific information may be provided, along with the other process information in the ISA Summary. Design basis events and safety parameter limits should be given. Methods, data, and results of analysis showing compliance with these design bases should be given for individual processes and facilities.

10 CFR 70.64 states that the design process must be based on defense-in-depth principles, and must incorporate, to the extent practicable, preference for engineered controls over administrative controls, and reduction of challenges to IROFS. Because of this regulation, new facilities with system safety designs lacking defense-in-depth, consisting of purely administrative controls, or relying on IROFS that are frequently or continuously challenged, are not acceptable, unless justification is provided showing that alternatives achieving the design criteria are not feasible.

5. TEAM QUALIFICATIONS AND ISA METHODS

The ISA teams [10 CFR 70.62(c)(2)] and their qualifications as stated in the ISA Summary are acceptable if the following criteria are met:

a. The ISA team has a team leader who is formally trained and knowledgeable in the ISA methodology chosen for the hazard and accident evaluations. In addition, the team leader should have an adequate understanding of all process operations and hazards under evaluation, but should not be the responsible, cognizant engineer or expert for that process.

b. At least one member of the ISA team has thorough, specific, and detailed experience in the process under evaluation.

c. The team represents a variety of process design and safety experience in those particular safety disciplines relevant to hazards that could credibly be present in the process, including, if applicable, radiation safety, nuclear criticality safety, fire protection, and chemical safety disciplines.

d. A manager provides overall administrative and technical direction for the ISA.

The description of the ISA method(s) is acceptable if the following criteria are met:

a. Hazard Identification Method. The hazard identification method selected is considered acceptable if it:

   i. Provides a list of materials (radioactive, fissile, flammable, and toxic) and conditions that could result in hazardous situations (e.g., loss of containment of licensed nuclear material). The list includes maximum intended inventory amounts and the location of

the hazardous materials at the facility. [1]

ii. Determines potential interactions between materials or conditions that could result in hazardous situations.

b. Process Hazard Analysis Method. The method for performing process hazard analysis is acceptable if it consists of selecting one of the individual methods described in NUREG-1513 in accordance with the selection criteria of that document. Individual methods not described in NUREG-1513 may be acceptable provided that:

i. Criteria are provided for their use for an individual process that are consistent with the principles of the selection criteria in NUREG-1513.

ii. It adequately addresses all the hazards identified in the hazard identification task. If an identified hazard is eliminated from further consideration, such action is justified.

iii. It provides reasonable assurance that the applicant can identify all significant accident sequences (including the IROFS used to prevent or mitigate the accidents) that could exceed the performance requirements of10 CFR 70.61. [2]

iv. It takes into account the interactions of identified hazards and proposed IROFS, including system interactions that could result in an accident sequence whose consequences could exceed the performance requirements of 10 CFR 70.61.

v. It addresses all modes of operation, including startup, normal operation, shutdown, and maintenance.

vi. It addresses hazards resulting from process deviations (e.g., high temperature, and high pressure); initiating events internal to the facility (e.g., fires or explosions); and hazardous credible external events (e.g., floods, high winds, earthquakes, and airplane crashes). The applicant provides justification for determinations that certain events are not credible and, therefore, not subject to the likelihood requirements of 10 CFR 70.61.

vii. It adequately considers initiation of, or contribution, to accident sequences by human error through the use of human-systems interface analysis or other appropriate methods.

viii. It adequately considers common mode failures and system interactions in evaluating systems that are to be protected by double-contingency.

ix. The ISA Summary provides justification that the individual method would effectively accomplish ii through viii, above.

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[1] At a minimum, the following hazardous materials should be included in the inventory list if present on-site: ammonia; fines (uranium oxide dust, beryllium); flammable liquids and gases; fluorine; hydrofluoric acid; hydrogen; nitric acid; organic solvents; propane; uranium hexafluoride; and Zircalloy.

[2] The release of hazardous chemicals is of regulatory concern to NRC only to the extent that such hazardous releases result from the processing of licensed nuclear material or have the potential for adversely affecting radiological safety.

c. Consequence Analysis Method. The methods used for ISA consequence evaluation, as described in the ISA Summary are acceptable if:

i. They are consistent with the approaches described in the Nuclear Fuel Cycle Facility Accident Analysis Handbook (NUREG/CR-6410, March 1998); and

ii. Their use of generic assumptions and data is reasonably conservative for the types of accidents analyzed.

d. Likelihood Evaluation Method. The method for evaluation of the likelihood of accident sequences, as described in the ISA Summary, is considered acceptable if:

i. The method clearly shows how each designated IROFS acts to prevent, or mitigate the consequences to an acceptable level, of the accident sequence being evaluated.

ii. When multiple IROFS are designated for an accident sequence, the method considers the interaction of all such IROFS, as in a logic diagram or tabulation, that accounts for the impact of redundancy, independence, and surveillance, to correct failures on the likelihood of occurrence of the accident.

iii. The method has objective criteria for evaluating, at least qualitatively, the likelihood of failure of individual IROFS. Such likelihood criteria should include the following, when applicable: means to limit potential failure modes; the magnitude of safety margins; the type of engineered equipment (active or passive) or human action that constitutes the IROFS; and the types and safety grading, if any, of the management measures applied to the IROFS.

iv. Finally, the method evaluates each accident sequence as unlikely, highly unlikely, or neither, as defined by the applicant, in accordance with subsection 3.4.3.2, Item 7, of this chapter.

v. For nuclear criticality accident sequences, the method evaluates compliance with 10 CFR 70.61(d). That is, even in a facility with engineered features to limit the consequences of nuclear criticalities, preventive control(s) must be in place that are sufficient to assure that the likelihood of criticality is controlled to be Ahighly unlikely.@ A moderately higher standard of likelihood may be permitted in preventing such events, consistent with ANSI/ANS Standard 8.10. In particular, criticality cannot result from any single IROFS failure. In addition, potential criticality accidents must meet an approved margin of subcriticality for safety. Acceptance criteria for such margins are reviewed as programmatic commitments, but the ISA methods must consider and the ISA Summary must document the actual magnitude of those margins when they are part of the reason why the postulated accident sequence resulting in criticality is highly unlikely.

One acceptable method of likelihood evaluation is described in Appendix A.

6. DESCRIPTIVE LIST OF ALL IROFS

The Alist describing items relied on for safety@ required by 10 CFR 70.62(c)(vi) is acceptable if:

1) It includes all IROFS in the identified high- and intermediate- consequence accident sequences; and

2) The description of the IROFS includes management measures applied to it (including the safety grading), characteristics of its preventive, mitigative, or other safety function, and assumptions and conditions under which the item is relied on to support compliance with the performance requirements of 10 CFR 70.61. If information on any safety limits and safety margins associated with an IROFS is not provided in the ISA Summary, then it must be available for review in ISA documentation on-site.

The above acceptance criteria are explained in greater detail below.

1) ALL ITEMS: The primary function of the list describing each IROFS is to document the safety basis of all processes in the facility. This list assists in assuring that the items are not degraded without a justifying safety review. Thus the key feature of this list is that all IROFS are included. To be acceptable, no item, aspect, feature, or property of the processes that is needed to show compliance with the safety performance requirements of the regulation may be left off this list. IROFS may be hardware with a dedicated safety function or hardware with a property that is relied on for safety. Thus IROFS may be the dimension, shape, capacity, or composition of hardware. The ISA Summary need not provide a breakdown of hardware IROFS by component or identify all support systems. However, the ISA documentation maintained on-site, such as system schematics and/or descriptive lists, should contain sufficient detail about items within a hardware IROFS, such that it is clear to the reviewer and the applicant, what structure, system, equipment or component is included within the hardware IROFS boundary and would therefore be subject to management controls specified by the applicant. Some examples of items within a hardware IROFS are detectors, sensors, electronics, cables, valves, piping, tanks, dykes, etc. In addition, ISA documentation should also identify essential utilities and support systems on which the IROFS depends to perform its intended function. Some examples of these are backup batteries, air supply, steam supply, etc. In some processes, the frequency of demands made on IROFS must be controlled or limited to comply with 10 CFR 70.61. In such processes, whatever features are needed to limit the frequency of demands are themselves IROFS.

2) THE DESCRIPTIONS OF ITEMS: The essential features of each IROFS should be described. Sufficient information should be provided about engineered hardware controls to permit an evaluation that, in principle, controls of this type will have adequate reliability. Because the likelihood of failure of items often depends on safety margins, the safety parameter controlled by the item, the safety limit on the parameter, and the margin to true failure should, in general, be described. For IROFS that are administrative controls, the nature of the action or prohibition involved must be described sufficiently to permit an understanding that, in principle, adherence to it should be reliable. Features of the IROFS that affect its independence from other IROFS, such as reliance on the same power supplies, should be indicated.

   The description of each IROFS within ISA documentation should identify its expected function, conditions needed for the IROFS to reliably perform its function, and the effects of its failure. The description of each IROFS within an ISA Summary should identify what management measures, such as maintenance, training, configuration management, etc., are applied to it. If

a system of graded management measures is used, the grade applied to each control should be determinable from information provided in an ISA Summary. The reliability required for an IROFS is proportionate to the amount of risk reduction relied on. Thus the quality of the management measures applied to an IROFS may be graded commensurate with the reliability required. The management measures shall assure that IROFS are designed, implemented, and maintained, as necessary, to be available and reliable to perform their function when needed. The degree of reliability and availability of IROFS assured by these measures should be consistent with the evaluations of accident likelihoods. In particular, for redundant IROFS, all information necessary to establish the average vulnerable outage time is required in order to maintain acceptable availability. Otherwise failures must be assumed to persist for the life of the plant. In particular, the time interval between surveillance observations or tests of the item should be stated, since restoration of a safe state cannot occur until the failure is discovered.

One example of a tabular description of IROFS meeting these criteria is Table A-12, in Appendix A.

7. QUANTITATIVE STANDARDS FOR CHEMICAL CONSEQUENCES

The applicant=s description in the ISA Summary of proposed quantitative chemical exposure standards used to assess consequences from acute chemical exposure to licensed material or chemicals incident to the processing licensed material is acceptable if:

a. There are unambiguous quantitative standards, for each of the applicable hazardous chemicals meeting the criteria of 10 CFR 70.65(b)(7) on site, corresponding to, and consistent with, the quantitative standards in each of the following 10 CFR sections: 70.61(b)(4)(i), 70.61(b)(4)(ii), 70.61(c)(4)(i), and 70.61(c)(4)(ii).

b. The quantitative standard of 10 CFR 70.61(b)(4)(i) addresses exposures that could endanger the life of a worker. The applicant is appropriately conservative in applying the language "could endanger," so as to include exposures that would result in death, consistent with the methods used for the U.S. Environmental Protection Agency “Acute Exposure Guidelines.”

c. The quantitative standards for 10 CFR 70.61(b)(4)(ii) and 10 CFR 70.61(c)(4)(i) will correctly categorize, as such, all exposures that could lead to irreversible or other serious, long-lasting health effects to individuals. As with (b), above, the standard selected should have appropriate conservatism.

d. The quantitative standard for 10 CFR 70.61(c)(4)(ii) will correctly categorize, as such, all exposures that could cause mild transient health effects to an individual.

The staff finds the use of the Emergency Response Planning Guidelines (ERPG) established by the American Industrial Hygiene Association, the Acute Exposure Guideline Levels (AEGL)established by the National Advisory Committee for Acute Guideline Levels for Hazardous Substances and exposure limits established by the Occupational Safety and Health Administration (OSHA) or contained in International Standards Organization (ISO) standards to be acceptable. If the applicant does not use a published exposure standard, or if a chemical has an unknown exposure standard, the ISA Summary must describe how an alternate exposure standard was

established for use in the ISA. The ISA Summary must list the actual exposure values for each chemical, the source of the data (e.g., ERPG, AEGL, ISO, etc.) and provide information or a reference justifying that they meet the acceptance criteria stated above.

8. LIST OF SOLE IROFS

The descriptive list in the ISA Summary that identifies all IROFS that are the sole item for preventing or mitigating an accident sequence is acceptable if it includes:

a) a descriptive title of the IROFS;

b) an unambiguous and clear reference to the process to which the item applies; and

c) clear and traceable reference to the description of the item as it appears in the full list of all IROFS.

9. DEFINITIONS OF UNLIKELY, HIGHLY UNLIKELY AND CREDIBLE

10 CFR 70.65 requires that the applicant=s ISA Summary provide definitions of the terms unlikely, highly unlikely, and credible. The applicant=s definitions of these terms are acceptable if, when used with the applicant=s method of assessing likelihoods, they provide reasonable assurance that the performance requirements of 10 CFR 70.61 can be met. The applicant=s method of likelihood evaluation and the definitions of the likelihood terms are closely related. Qualitative methods require qualitative definitions. Such a qualitative definition would identify the qualities of IROFS, controlling an accident sequence, that would qualify that sequence as Aunlikely@ or Ahighly unlikely.@

An applicant may use quantitative methods and definitions for evaluating compliance with 10 CFR 70.61, but nothing in this SRP should be construed as an interpretation that such methods are required. The reviewer should focus on objective qualities and information provided concerning accident likelihoods.

10 CFR 70.61 requires that credible high-consequence events be highly unlikely. Thus the meaning of the phrase Ahighly unlikely@ is on a per-event basis. The same is true for the terms Aunlikely@ and Acredible.@ Hence, applicant definitions should be on a per-event basis. The events referred to are occurrences of consequences, which are herein synonymous with the phrase Aaccident sequence.@ This is important to recognize since there may be hundreds of potential accident sequences identified in an ISA. Thus the likelihood of each individual sequence must be quite low.

ACCEPTANCE CRITERIA FOR THE DEFINITION OF ACREDIBLE@

10 CFR 70.65 requires that the applicant define the term Acredible.@ This term Acredible@ is used in 10 CFR 70.61 which requires that all credible accident sequences whose consequences could exceed the performance requirements of 10 CFR 70.61 must be controlled to be unlikely or highly unlikely, as appropriate. If an event is not credible, then IROFS are not required to prevent or mitigate the event. Thus, to be Anot credible@ could be used as a criterion for exemption from use of IROFS. There is a danger of circular reasoning here. In the safety program embodied in the rule, the fact that an event is >not credible= must not depend on any plant feature that could

credibly fail to function, or be rendered ineffective as a result of a change to the system. Each plant feature that is needed to assure that accident events are sufficiently unlikely is an IROFS. There must be high assurance, provided by management measures, that such features are not removed or rendered ineffective during system changes. One cannot claim that a process does not need IROFS because it is Anot credible@ because of characteristics provided by IROFS.

Three independent acceptable sets of qualities, any one of which could define an event as not credible, are:

1. An external event whose frequency of occurrence can conservatively be estimated as less than once in a million years.

2. A process deviation that consists of a sequence of many unlikely human actions or errors for which there is no reason or motive. In determining that there is no reason for such actions, consideration must have been given to a wide range of possible motives, short of intent to cause harm. Necessarily, no such sequence of events can ever have actually happened in any fuel cycle facility.

3. Process deviations for which there is a convincing argument, based on physical laws, that they are not possible, or are unquestionably extremely unlikely. The validity of the argument must not be dependent on any feature of the design or materials controlled by the plant=s system of IROFS or management measures.

The implication of the use of Acredible@ in 10 CFR 70.61 is that events that are not Acredible@ may be neglected. For this to be acceptable on a risk basis, unless the event is impossible, it must be of negligible likelihood. Negligible likelihood means sufficiently low that, considering the consequences, the addition to total risk is small. Note that consideration must thus be given to how many such events have, in fact, been neglected. An applicant may demonstrate, by quantitative reasoning, that a particular event is of negligible frequency. Such a demonstration must be convincing despite the absence of designated IROFS. Typically, this can only be achieved for external events known to be extremely unlikely.

ACCEPTANCE CRITERIA FOR QUALITATIVE DEFINITIONS OF LIKELIHOOD

If the applicant=s definitions are qualitative, then they are acceptable if they:

a. Are reasonably clear and based on objective criteria; and

b. Can reasonably be expected to consistently distinguish accidents that are highly unlikely from those that are merely unlikely.

By the phrase Aobjective criteria@ is meant the extent to which the method relies on specific identifiable characteristics of a process design, rather than subjective judgments of adequacy. Objective criteria are needed to achieve consistency. By consistency is meant the degree to which the same results are obtained when the method is applied by different analysts. This is important, to maintain an adequate standard of safety, because ISAs of future plant modifications may be performed by individuals not involved in the initial ISA.

Reliability and Availability Qualities

Qualitative methods of evaluating the likelihood of an accident sequence involve identifying the reliability and availability qualities of each of the events that constitute the sequence. The following lists of qualities are not necessarily complete, but contain many of the factors most commonly encountered. Some of these qualities relate to the characteristics of individual IROFS, such as:

1) Safety margin in the controlled parameter, compared with process variation and uncertainty;
2) Whether the IROFS is an active engineered control, a passive engineered control, an administrative control, or an enhanced administrative control;
3) The type and grade of management measures applied to the control;
4) Fail-safe, self-announcing, or surveillance measures to limit down time;
5) Failure modes;
6) Demand rate; and
7) Failure rate.

Other reliability qualities relate characteristics of the IROFS or system of IROFS, protecting against the accident sequence as a whole, such as:

8) Defense-in-depth;
9) Degree of redundancy;
10) Degree of independence;
11) Diversity; and
12) Vulnerability to common-cause failure.

Methods of likelihood evaluation, and the definitions of the rule=s likelihood terms, may mix qualitative and quantitative information. Certain types of objective quantitative information may be available concerning specific processes in a plant. Some examples of such objective quantitative information are:

1) Reports of failure modes of equipment or violations of procedures recorded in maintenance records or corrective actions programs;
2) The time intervals at which surveillance is conducted to detect failed conditions;
3) The time intervals at which functional tests or configuration audits are held;
4) For a fail-safe, monitored, or self-announcing IROFS, the time it takes to render the system safe; and
5) Demand rates (i.e., how frequent are the demands on an IROFS to perform). Some situations amount to effectively continuous demand.

Such items of quantitative information should be considered in evaluating the likelihood of accident sequences, even in purely qualitative evaluations. For example, knowing the value to which down time is limited by surveillance can indicate that a system=s availability is extremely high. For redundant systems, such high availability can virtually preclude concurrent independent failures of the multiple controls.

Acceptance Criteria for Likelihood Indexing Methods

One acceptable type of definition for the likelihood terms Aunlikely@ and Ahighly unlikely@ could be based on a risk-indexing method. Such a method is described in the example in Appendix A. The

example described in Appendix A is intended to rely primarily on a qualitative evaluation of reliability/availability factors. In such methods, qualitative characteristics of the system of IROFS, such as those listed above, are used to estimate a quantitative likelihood index for each accident sequence. The definition of Aunlikely@ then is an acceptable limit on this likelihood index.

Acceptance Criteria for Purely Qualitative Methods

A purely qualitative method of defining Aunlikely@ and Ahighly unlikely@ is acceptable if it incorporates all of the applicable reliability and availability qualities to an appropriate degree. For example, one statement of applicable qualities is double-contingency protection:

Double-Contingency Protection: The quality of a process design that incorporates sufficient factors of safety to require at least two unlikely, independent, and concurrent changes in process conditions before a criticality accident is possible.

Double-contingency addresses explicitly several reliability / availability qualities, namely:

Factors of safety:	Safety margins
At least two:	Redundancy
Unlikely:	Low failure rate, low down time of one of two controls
Concurrent:	Low down time
Independent:	Independence
Process conditions:	Physical events, not virtual human errors

One acceptable definition of highly unlikely is a system of IROFS that possesses double-contingency protection, where each of the applicable qualities is present to an appropriate degree. For example, as implied by the modifier, Aat least,@ sometimes more than just two-fold redundancy may be appropriate.

A qualitative method may also be proposed for defining Aunlikely.@ Such a qualitative method might simply list various combinations of reliability qualities for a system of IROFS that would qualify as Aunlikely.@ For example, a single high-reliability IROFS, such as an engineered hardware control with a high grade of applicable management measures, might qualify to be considered Aunlikely to fail.@ Systems relying on administrative controls would normally have to make use of enhancing qualities such as large safety margins and redundancy, to qualify as Aunlikely to fail.@ A single simple administrative control, regularly challenged, without any special safety margin or enhancement, where a single simple error would lead to an accident, would not qualify as Aunlikely@ to fail.

ACCEPTANCE CRITERIA FOR QUANTITATIVE DEFINITIONS OF LIKELIHOOD

An applicant may choose to provide quantitative definitions of the terms “unlikely” and “highly unlikely.” Quantitative guidelines are developed below. These guidelines serve two purposes: (1) they can be used as acceptance criteria for quantitative definitions, if provided; and (2) they provide guidance to the reviewer when objective quantitative reliability / availability information exists.

The goals from which these quantitative guidelines were derived are for specific types of accidents. Therefore the guidelines should not be used for accidents that differ significantly from

these specific types. The high-consequence guideline, for example, is based on a goal of no inadvertent nuclear criticalities. Thus, this guideline should be used for accidents whose consequences are similar to a nuclear criticality accident (i.e., one where a few fatal or near fatal worker doses may occur). For substantially more severe high-consequence accidents, more stringent likelihood criteria would be acceptable. For less severe high-consequence accidents, less stringent criteria may be applied. Quantitative guidelines are derived from goals, not limits, and have been judged to be the highest values consistent with those goals.

QUANTITATIVE GUIDELINES

Quantitative definitions of likelihood are based on NRC strategic risk performance goals. Quantitative likelihood values are an appropriate fraction of the risks of other industrial accident risks in the U.S., and conform to comparable quantitative values already used in other countries for regulation of nuclear materials facilities. A discussion of quantitative guidelines here does not imply that quantitative demonstration of compliance with 10 CFR 70.61 is required.

Highly Unlikely

The guideline for acceptance of the definition of Ahighly unlikely@ has been derived as the highest acceptable frequency that is consistent with a goal of having no inadvertent nuclear criticality accidents, and no accidents of similar consequences, in the industry. To within an order of magnitude, this is taken to mean a frequency limit of less than one such accident in the industry every 100 years. This has been translated below into a guideline limiting the frequency of individual accidents to 10^{-5} per-event per-year. As the goal is to have no such accidents, accident frequencies should be reduced substantially below this guideline when feasible.

Unlikely

Intermediate-consequence events include significant radiation exposures to workers; those exceeding 0.25 Sieverts (25 rem). The NRC's goal is for there to be no increase in the rate of such significant exposures. This has been translated below into a guideline of 4×10^{-5} per-event per-year. This guideline may be more generally considered as a range between 10^{-4} and 10^{-5} per-event per-year since exact frequencies at such levels cannot accurately be determined.

Quantitative Guidelines for use with Acceptance Criteria

The applicant=s quantitative definitions of the terms “unlikely” and “highly unlikely,” as applied to individual accident sequences identified in the ISA, are acceptable for showing compliance with 10 CFR 70.61, if they are reasonably consistent with the following quantitative guidelines:

Likelihood term of '70.61	Guideline
Unlikely	Less than 4×10^{-5} per-event per-year
Highly Unlikely	Less than 10^{-5} per-event per-year

The stated quantitative guidelines are used to define the largest likelihood values that would be acceptable limits. Definitions based on lower limits are also acceptable.

3.5 REVIEW PROCEDURES

Organization of the reviews addressed by this SRP will differ depending on the scope of the documents submitted. For a license application, renewal, or amendment application containing a new or revised chapter addressing Safety Program and ISA commitments, there may only be a primary ISA reviewer. However, for an initial ISA Summary submittal, this primary ISA reviewer will be assisted by specialists in the various safety disciplines and management measures. An ISA Summary update submitted as part of an amendment for a process that has hazards in multiple disciplines would also require a team approach. In general, there will be a primary ISA reviewer who evaluates generic methods, risk, and reliability criteria used in the ISA, and generic information about individual processes. This primary reviewer will be assisted by secondary reviewers who evaluate selected individual accidents, and advise on the completeness of the accident list for specific safety disciplines.

3.5.1 Acceptance Review

For review of Safety Program commitments, including commitments pertaining to the ISA and ISA Summary, (a renewal or amendment application), the primary ISA reviewer will conduct a review to determine if the submittal contains appropriate information addressing each of the areas of review identified in Section 3.3.1 of this chapter. If the application does not contain sufficient information addressing the areas of review to permit a safety evaluation, then the application will not be accepted for review.

For an ISA Summary, the primary ISA reviewer will also conduct an acceptance review to determine whether the document submitted contains sufficient information addressing the Areas of Review noted in section 3.3.2, including specifically each of the elements required by 10 CFR 70.65(b), to permit an evaluation of safety for compliance with the regulations. If insufficient information is not present, the ISA Summary will not be accepted.

3.5.2 Safety Evaluation

3.5.2.1 Evaluation of Safety Program and ISA Commitments

The staff reviews the descriptions and commitments to program elements in the application or other documents for the Areas of Review described in section 3.3.1, to ascertain whether the program elements are sufficient to meet the acceptance criteria of section 3.4.3.1. The ISA reviewer must coordinate his or her review, with reviews being conducted under other chapters of this SRP.

3.5.2.2 Evaluation of ISA Summary

Evaluation of the ISA Summary to determine if the acceptance criteria of section 3.4 have been met would normally be performed by a team consisting of a primary reviewer together with specialists in each category of accidents. These categories of accidents depend on the facility, but, in general, are: nuclear criticality, fires, chemical accidents, and radiological accidents. If external-event analysis is complex, specialists may be employed to review these separately, as well. The primary ISA reviewer would normally evaluate the acceptability of the generic elements of the ISA Summary, such as site and facility descriptions, ISA methods, criteria, and consequence and likelihood definitions. However, each specialist should also review these elements to obtain information in support of his / her own evaluations.

In contrast to these generic ISA elements, process-specific information is needed by, and must be acceptable to, all of the specialists. Thus the process descriptions in the ISA Summary should be evaluated by all of the team members.

Reviews of accident sequence descriptions and the likelihood and consequence information showing compliance with 10 CFR 70.61 should be undertaken by separate specialists for each category of accidents. These accident categories are: nuclear criticalities, fires, radiological releases, and chemical accidents. As indicated in Appendix A, one acceptable format for the ISA Summary is to tabulate or give logic diagrams for accident sequences in each of these groups, separately.

After a preliminary team review of the ISA Summary, a visit to the facility would normally be made for familiarization with the 3-D geometry of process equipment to review components of the ISA and to address any issues that arose during review of the ISA Summary.

To select a sub-set of the accident sequences reported in the ISA Summary for more detailed review, the reviewer should look at the applicant's tabulation of high and intermediate risk accident sequences and the types of IROFS designated for each. High-consequence accident sequences protected by administrative controls should be examined very carefully, whereas intermediate-consequence accident sequences protected by redundant passive engineered controls should warrant a lesser degree of scrutiny. Selection of specific accident sequences and IROFS for more detailed evaluation should then be made using the following approach.

The staff should evaluate potential accidents using information supplied in the ISA Summary. The applicant=s method for determining accident sequence may provide information sufficient for this purpose. The NRC staff may make an evaluation of the accidents using qualitative screening criteria analogous to Table A-6 in Appendix A. Other more rigorous reliability or consequence analyses may be performed as judged necessary. Based on this, accidents will be categorized. Engineered and administrative controls for accidents appearing in the highest category may be selected for review in greater detail. While on-site, staff should select a small sample of accident sequences determined by the applicant to either result in less than intermediate consequences or be not credible for specific evaluation.

From the list of the IROFS, the reviewer should categorize IROFS so that items of a similar nature are grouped together. The reviewer should then assure that he has a full understanding of one or more prototype IROFS selected from each category. For these selected prototypes, the reviewer may, if necessary, request additional information to reach such a full understanding of particular IROFS. For complex processes, it may be necessary to visit the plant to reach an adequate understanding of how the IROFS work for the process.

3.5.2.3 Onsite ISA Review

The reviewer or team of reviewers should perform a horizontal and several vertical slice reviews of the ISA onsite. Based on a horizontal review of a plant process or processes identified in the ISA Summary, the reviewer should be able to make a determination that the applicant has indeed, in all likelihood, identified all potential accidents that are credible and could result in high and intermediate consequences. In addition to the horizontal review of the ISA documentation, the reviewer should also perform vertical slice reviews of the ISA documentation. The number of vertical slice reviews needed would depend on the number of accident sequences in specific

process that could result in high and intermediate consequence accidents, the diversity of the types of processes at the facility, and the initial results of the horizontal and vertical slice reviews. For most fuel fabrication facilities, the reviewer should plan on conducting a vertical slice review for 5-10 NCS-significant processes, 1-3 fire-significant processes, and 1-3 chemical/radiological-significant processes. In planning to conduct vertical slice reviews, the reviewer should select processes that; (1) have relatively high consequence and/or likelihood accidents, (2) do not appear to have very robust IROFS, (3) are different and diverse from each other, and (4) are different from the ones included as examples by the applicant in the ISA Summary.

ISA METHODS REVIEW

The purpose of this on-site methods review is to clarify any questions the reviewer may have concerning ISA methods and procedures after his/her review of the ISA Summary. Thus in reviewing process-specific information in the ISA Summary and on-site, processes and accidents should be selected that will aid in answering these questions. The purpose of the ISA method review is also to assure that the licensee has adequately applied the ISA methods described in the ISA Summary. The reviewer should examine any procedures, checklists, or guidance documents that the applicant may have on-site as guidance to ISA Team members to assure that his understanding of ISA methods is correct. The reviewer should then examine the ISA documentation showing the applicant's application of the ISA methods as part of the horizontal and vertical slice reviews discussed below.

HORIZONTAL REVIEW

The basic purpose of the horizontal review is to verify that the ISA at the facility has covered all required processes; and that it has achieved compliance with 10 CFR 70.61. This does not require an absolute checkoff of ISA documentation against the full list of processes to be covered, but does mean that a substantial fraction of the processes should receive a brief examination.

The review should focus on those areas of the ISA documentation that address questions or issues resulting from the review of the ISA Summary. If the ISA Summary included sufficient process-specific information for certain processes, then these may not need further examination on-site. In particular, the review should look for types of processes, safety designs, IROFS, and management measure implementations not identified in the ISA Summary. For example, ISA documentation related to hardware IROFS, such as system schematics and/or descriptive lists, should contain sufficient detail about hardware IROFS, such that it is clear to the reviewer what components, such as cables, detectors, alarms, valves, piping, etc., are included within the hardware IROFS system boundary and would therefore be subject to management controls specified by the applicant. In addition, such documentation should also identify support systems, such as backup batteries, air supply, steam supply, etc., on which the IROFS depends to perform its intended function.

The ISA Summary review will have categorized accidents according to their consequences, likelihoods and IROFS. The processes selected for vertical slice reviews should be selected based on these categories.

VERTICAL SLICE REVIEW

The purpose of the vertical slice review is to examine the ISA performed on a selected subset of processes in order to more fully understand the meaning and effectiveness of the applicant's ISA methods. The subset should be selected following review of the ISA Summary, and should: (1) be based on the magnitudes of the accident consequences and/or likelihoods and the robustness of the IROFS, (2) involve diverse processes, and (3) avoid, to the extent possible, including processes used by the applicant in its ISA Summary as examples of application of ISA methods. For example, an applicant's methods of likelihood and consequence evaluation may distinguish between designs whose compliance with the performance requirements is clear, and others which are less so. Reviewers should avoid selecting processes for detailed review from the robust set, but rather select more from those whose adequacy is less robust. The vertical slice review should address specific questions of methods or implementation of the ISA. If the applicant's methods are evaluated as effective in these selected cases, then there is greater assurance that they will be effective for other processes. If questions or weaknesses are discovered which may be of a generic nature, then it may be necessary to add more processes to the subset for examination. However, the fact that there is a specific question with respect to the ISA of one process may not imply that there is a generic question requiring further examination. The purpose is not complete verification of ISA implementation.

Another criterion for selecting a process is prior accident and precursor experience showing vulnerability to design weakness. For example, 21 of 22 process criticality accidents have occurred in solution systems. Exothermic chemical reaction processes have frequently resulted in accidents. Thus an effort would be made to include these types of processes in those for detailed review. Another criterion for selection is safety designs where high reliability is inherently difficult

to achieve. Examples are: 1) designs with high dependence on correct operator action, and 2) complex active engineered control systems.

Each vertical slice review should include: (1) familiarization of the reviewer with the safety design of the selected process, and (2) examination of all on-site documentation related to the ISA of that process. If the content of the documentation leaves certain issues unclear, interviews with facility personnel may be necessary. The review should focus on the information on-site that is not provided in the ISA Summary but is key to understanding compliance with 10 CFR 70.61 requirements.

The review should focus on evaluating the ISA of the particular process against the acceptance criteria of this chapter. In particular it should evaluate the effectiveness of the applicant's methods for identifying accidents, evaluating consequences, and evaluating likelihood as applied in this particular process. It should focus on methodological areas and questions raised during review of the ISA Summary.

Finally, if it appears to be useful, the reviewer may apply his own independent evaluation of compliance with 10 CFR 70.61 using appropriate methods selected from NUREG-1513, the Appendices to this chapter, or other agency guidance. The purpose of such an independent review is to identify strengths and weaknesses of the applicant's methods or implementation practices, not simply to check compliance in this one case per se.

The reviewer should take care to document findings and evaluations made during this process.

3.6 EVALUATION FINDINGS

The reviewer verifies that the information submitted by the applicant is sufficiently complete so that compliance with the regulations can be evaluated. For each requirements statement in the regulation addressing the ISA Summary, the evaluation findings should include a brief statement as to why the information submitted demonstrates compliance. There should be a finding statement, following the evaluation of each area of review, stating how the information submitted in that area supports the related regulatory requirement. Specifically, the staff findings in the Safety Evaluation Report (SER) should state conclusions of the following types:

General conclusion resulting from staff evaluation of safety program commitments:

> The staff concludes that the applicant=s Safety Program, if established and maintained pursuant to 10 CFR 70.62, is adequate to provide reasonable assurance that IROFS will be available and reliable to perform their intended safety function when needed and in the context of the performance requirements of 10 CFR 70.61.

There should be general findings, for each of the areas of review, stating how the applicant=s information demonstrates compliance with the acceptance criteria of section 3.4.3.1. If staff finds that the acceptance criteria are not met, a license condition rectifying the deficiency should be recommended. If the applicant has submitted an adequate explanation of an alternate way of complying with the regulations, the staff evaluation should contain a finding that the alternative is acceptable for meeting the basic regulatory requirement addressed.

General conclusions resulting from staff evaluation of an ISA Summary:

Many hazards and potential accidents can result in unintended exposure of persons to radiation, radioactive materials, or toxic chemicals incident to the processing of licensed materials. The staff finds that the applicant has performed an ISA to identify and evaluate those hazards and potential accidents as required by the regulations. The staff has reviewed the ISA Summary and other information, and finds that it provides reasonable assurance that the applicant has identified IROFS and established engineered and administrative controls to ensure compliance with the performance requirements of 10 CFR 70.61. Specifically, the staff finds that the ISA results, as documented in the ISA Summary, provide reasonable assurance that the IROFS, the management measures, and the licensee=s programmatic commitments will, if properly implemented, make all credible intermediate consequence accidents unlikely, and all credible high-consequence accidents highly unlikely.

Findings should be made, concerning any specific requirements statements in 10 CFR 70 that address the nine elements in the ISA Summary. In particular, these findings should include statements, concerning compliance with the requirements of 10 CFR 70.64 (regarding new facilities and new processes at existing facilities), for those processes to which they are applicable.

Findings may be made concerning compliance of specific processes with requirements of 10 CFR 70.61 or other parts of the regulation, for those processes that receive specific detailed review. However, such findings should be limited to a finding, of reasonable assurance, that a process having the IROFS, as described in the ISA Summary, is capable of meeting the requirements, if properly implemented, operated, and maintained.

3.7 REFERENCES

American Institute of Chemical Engineers (AIChE), AGuidelines for Hazard Evaluation Procedures, Second Edition with Worked Examples,@ New York, September 1992.

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